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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,871	09/18/2003	Wayne P. Fitzmaurice	1328-004A	3169

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EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT PAPER NUMBER

1638

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/668,871	FITZMAURICE, WAYNE P.	
	Examiner	Art Unit	
	Keith O. Robinson, Ph.D.	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 19-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. The cancellation of claims 1-18 and the addition of new claims 19-22, filed December 9, 2005, have been received and entered in full.
2. Claims 19-22 are pending.

### ***Response to Arguments***

3. The Examiner objected to claims 13 and 14 in the previous Office Action mailed September 9, 2005. In view of Applicant's cancellation of claims 1-18 in the 'Amendments to the Claims' filed December 9, 2005, this objection is moot.

The objection to the specification filed in the previous Office Action mailed September 9, 2005, is withdrawn in view of Applicant's amendments (see 'Amendments to the Specification', pages 2-3, filed December 9, 2005).

The terminal disclaimer filed on December 9, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 6,344,597 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The 35 U.S.C. § 112, first paragraph rejection of claims 11-14 for lack of written description and enablement, filed September 9, 2005, is moot due to Applicant's cancellation of claims 11-14 in the 'Amendments to the Claims' filed December 9, 2005.

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The 35 U.S.C. § 102 rejection of claims 12-13, filed September 9, 2005, is moot due to Applicant's cancellation of claims 12-13 in the 'Amendments to the Claims' filed December 9, 2005.

The 35 U.S.C. § 103 rejection of claim 14, filed September 9, 2005, is moot due to Applicant's cancellation of claim 14 in the 'Amendments to the Claims' filed December 9, 2005.

***Claim Rejections - 35 USC § 112, second paragraph***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim claims "pods" as a source of tissue wherein regenerable cells are produced. It is known in the art that *Nicotina* does not have pods. The removal of this word would obviate the rejection.

***Claim Rejections - 35 USC § 112, first paragraph – Written Description***

6. Claims 19-22 are rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had

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possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office Action filed September 9, 2005, pages 4-6, as applied to claims 11-14. Applicant's arguments filed December 9, 2005 have been fully considered but they are not persuasive.

Applicant argues that in addition to *N. excelsiana* being described, hybrids produced from *N. benthamiana* x *N. tabacum* and *N. occidentalis* TW91 x *N. umbratica* TW144 are described as well (see page 6, last paragraph to page 7, end of 1<sup>st</sup> paragraph).

This is not persuasive. The specification states, "TW47 and TW16 [the parents used to produce the hybrid *N. excelsiana*] accessions were each obtained from the USDA Tobacco Germplasm Collection in Oxford, NC" (see page 10, paragraph 0051), thus the hybrid is described because the parents are described. There is no such description of the parents of the *N. benthamiana* x *N. tabacum* and *N. occidentalis* TW91 x *N. umbratica* TW144 hybrids.

Applicant further argues that one skilled in the art, given a successful chromosome-doubled interspecific *Nicotiana* hybrid, can choose the greater biomass parent as the recurrent parent and backcross to form the sesquidiploid.

This is not persuasive. The above argument does not provide a written description for the broad genus of sesquidiploid progeny from chromosome-doubled interspecific *Nicotiana* hybrids. The specification only provides a written description for the interspecific hybrid *Nicotiana excelsiana*.

***Claim Rejections - 35 USC § 112, first paragraph – Enablement***

7. Claims 19-22 are rejected under 35 USC § 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the Office Action filed September 9, 2005, pages 6-9, as applied to claims 11-14. Applicant's arguments filed December 9, 2005 have been fully considered but they are not persuasive.

Applicant argues Table 3 of the specification provides for several alternative hybrids including *N. benthamiana* x *N. tabacum* and *N. occidentalis* x *N. umbratica* hybrids (see page 7, 2<sup>nd</sup> paragraph of the 'Remarks' filed December 9, 2005). This is not persuasive. As stated above, the specification states, "TW47 and TW16 [the parents used to produce the hybrid *N. excelsiana*] accessions were each obtained from the USDA Tobacco Germplasm Collection in Oxford, NC" (see page 10, paragraph 0051). There is no such description of the parents of the *N. benthamiana* x *N. tabacum* and *N. occidentalis* TW91 x *N. umbratica* TW144 hybrids, therefore, one skilled in the art would not know how to make the claimed invention. Also, on page 7, 1<sup>st</sup> paragraph of the previous Office Action filed September 9, 2005, it states that the specification provides evidence that progeny from interspecific *Nicotiana* hybrids (or sesquidiploid hybrids) may be genotypic specific.

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Applicant's argument regarding the number of backcross generations used to produce backcross progeny is persuasive (see page 7, last paragraph of 'Remarks' filed December 9, 2005).

Applicant's argument regarding the use of colchicine to restore fertility is persuasive (see page 8, 1<sup>st</sup> paragraph of 'Remarks' filed December 9, 2005).

Applicant has not addressed the unpredictability of the Davies reference regarding the somatic chromosome elimination in the genus *Nicotiana* (see page 7, last sentence to page 8, lines 1-4 of the previous Office Action filed September 9, 2005); therefore, the Examiner maintains the enablement rejection with regards to unpredictability as it would require undue trial and error experimentation to determine which, if any, the broad genus of *Nicotiana* plants used in the method did not have somatic chromosome elimination.

### ***Claim Rejections - 35 USC § 102***

8. Claims 20 and 21 are rejected under 35 USC § 102 (b) as being anticipated by McCray (Genetics 17: 660-673, 1932). The rejection is repeated for the reasons of record as set forth in the Office Action filed September 9, 2005, pages 9-10, as applied to claims 12-13. Applicant's arguments filed December 9, 2005 have been fully considered but they are not persuasive.

Applicant argues that the McCray reference does not teach the backcrossing of chromosome-doubled interspecific hybrids with a recurrent parent, but rather teaches

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the backcross of tri-hybrid species to a diploid parent (see page 9, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs of the 'Remarks' filed December 9, 2005).

This is not persuasive. McCray teaches *Nicotiana* hybrids produced by backcrossing a chromosome-doubled interspecific hybrid to a recurrent parent, wherein said hybrids are more vigorous and fertile. As the claim is written it reads on any seed or plant produced from a method of producing sesquidiploid progeny from chromosome-doubled interspecific *Nicotiana* hybrids. The term "high level of biomass" can be interpreted as "more vigorous and fertile" and the term "capacity for high level of systemic expression of heterologous protein" infers that the plant may or may not have the claimed trait. Thus, the plant disclosed by McCray would be indistinguishable from the claimed plant. See *In re Thorpe* and *In re Best* on pages 9-10 of the previous Office Action filed September 9, 2005.

### ***Claim Rejections - 35 USC § 103***

9. Claim 22 is rejected under 35 USC § 103 (a) as being unpatentable over McCray, in view of Applicant's admission on page 21, paragraph 0071 of the specification. The rejection is repeated for the reasons of record as set forth in the Office Action filed September 9, 2005, pages 10-11, as applied to claim 14. Applicant's arguments filed December 9, 2005 have been fully considered but they are not persuasive.



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Applicant argues that the plant taught by McCray is not a sesquidiploid and that McCray does not teach the tissue culturing of sesquidiploids (see page 10 of the 'Remarks' filed December 9, 2005).

This is not persuasive. As stated above, a sesquidiploid plant is an interspecific plant. McCray does teach an interspecific *Nicotiana* hybrid and even though it is not a sesquidiploid hybrid, it was produced by an interspecific cross as was the claimed invention. See *In re Thorpe*. The Examiner acknowledges that McCray does not suggest the tissue culturing of sesquidiploids; however, the Examiner has provided evidence via the specification that tissue culturing of *Nicotiana* is well known in the art (see page 10 of the previous Office Action filed September 9, 2005).

### ***Conclusion***

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

March 14, 2006

DAVID H. KRUSE, PH.D.  
PRIMARY EXAMINER  
